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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|------------------------------------------------------------------------------------------------|-------------|----------------------|---------------------|------------------|
| 10/536,860 | 01/06/2006 | Hana Golding | 65831 (47992) | 4611 |
| 46037 7590 09/04/2009 EDWARDS ANGELL PALMER & DODGE LLP PO BOX 55874 BOSTON, MA 02205 | | | | |
| EXAMINER | | | | |
| CHEN, STACY BROWN | | | | |
| ART UNIT | | PAPER NUMBER | | |
| 1648 | | | | |
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| 09/04/2009 | | PAPER | | |

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/536,860

Applicant(s)

GOLDING, HANA

Examiner

Stacy B. Chen

Art Unit

1648

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 24 July 2009.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,5,7,12-15,17,18 and 21 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,5,7,12-15,17,18 and 21 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 27 May 2005 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(c), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(c) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on July 24, 2009 has been entered. Claims 1, 5, 7, 12-15, 17, 18 and 21 are pending and under examination.

Claim Rejections - 35 USC § 103

2. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1, 5, 7, 12-15 and 17 remain rejected under 35 U.S.C. 103(a) as being unpatentable over Domínguez *et al.* (*Journal of Immunological Methods*, 1998, 220:115-221, "Domínguez") in view of Hooper *et al.* (US Patent 6,451,309, "Hooper").

Applicant's arguments have been carefully considered but fail to persuade. Applicant's substantive arguments are primarily directed to the following:

- Applicant argues that the combined teachings do not arrive at the claimed method that measures protection of cells against virus invasion by measuring a decrease in invasion by a candidate agent.

- In response to Applicant's argument, the combined teachings result in a method that looks at the ability of an antibody to interfere with the infection of cells by using a vaccinia virus/GFP infection marker. This translates to a method that measures protection of cells (*i.e.*, whether the antibody interferes with infection) against virus invasion (*i.e.*, vaccinia/GFP construct) by measuring a decrease in invasion (*i.e.*, determined by flow cytometry) by a candidate agent (*i.e.*, an antibody).
- Applicant asserts that the present method provides a quantitative determination of invasion, which is not possible with the individual or combined teachings of Domínguez and Hooper. Applicant argues that Domínguez merely teaches that vaccinia/GFP construct is useful as an infection marker, not as a marker that would be useful in providing a quantitative determination of invention. Applicant points to page 9 of the specification, Example I, which discloses that an ELISA assay enables quantitative determination of virus infectivity based on a readout measured against a standard curve.
- In response to Applicant's argument, the ELISA that is referred to in the specification is a process that takes place *after* the method steps of claim 1 are completed. The ELISA can be performed because the readout from the method of claim 1 is, in some embodiments, an enzymatic reaction resulting in substrate color change. Thus, the ELISA that enables quantitative determination of virus infectivity is a method step that is not instantly claimed. Even if it were claimed, Domínguez discloses that a number of marker genes can be inserted in the

vaccinia virus genome, and that their utility has been demonstrated in different experimental situations (thymidine kinase, guanine phosphoribosyl transferase, beta-galactosidase, etc.), see Domínguez, pages 115-116, bridging paragraph.

The use of those enzyme marker genes would enable the use of an ELISA quantitative determination of virus infectivity in a subsequent method step.

- Applicant asserts that the present method provides a prediction of virus lethality, which is not possible with the individual or combined teachings of Domínguez and Hooper. Applicant argues that the Hooper reference does not teach or suggest a reporter-based assay that demonstrates the protective activity of their monoclonal antibodies. Applicant points to page 10 of the specification and Example III, which discloses that *in vitro* neutralization assays are predictive of lethality.
- In response to Applicant's arguments, the specification discloses that a mouse lethality model (SCID mice) was used to show that *in vitro* neutralization assays correlated positively with significant difference in protective efficiency against lethal infection of mice with vaccinia. The ability of the *in vitro* neutralization assay as a predictor of virus lethality has nothing to do with the claimed method because the neutralization assay is not recited in the claims. The claimed method is what it is, regardless of further implications of performing the method. In other words, subsequent method steps that can be performed as a result of carrying out the claimed method, are not part of the claimed method. Therefore, the invention remains obvious over the prior art to one of ordinary skill at the time of the invention.

3. Claims 18 and 21 remain rejected under 35 U.S.C. 103(a) as being unpatentable over Domínguez *et al.* (*Journal of Immunological Methods*, 1998, 220:115-221, “Domínguez”) in view of Hooper *et al.* (US Patent 6,451,309, “Hooper”) as applied to claims 1 and 17 above, and further in view of Engelmayr *et al.* (*The Journal of Immunology*, 1999, 163:6762-6768, “Engelmayr”). Applicant’s arguments regarding this rejection have been addressed above. The rejection is maintained for reasons of record.

Conclusion

4. No claim is allowed.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Stacy B. Chen whose telephone number is 571-272-0896. The examiner can normally be reached on M-F (7:00-4:30). If attempts to reach the examiner by telephone are unsuccessful, the examiner’s supervisor, Gary Nickol can be reached on 571-272-0835. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

/Stacy B Chen/
Primary Examiner, Art Unit 1648